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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------|
| 09/917,058   | 07/27/2001  | Martha M. Murray     | 18989-001 CIP<br>(BWH-1CIP) | 2028             |
| 23628  | 7590        | 04/13/2004           | EXAMINER                    |                  |
| WOLF GREENFIELD & SACKS, PC<br>FEDERAL RESERVE PLAZA<br>600 ATLANTIC AVENUE<br>BOSTON, MA 02210-2211 |             |                      | PELLEGRINO, BRIAN E         |                  |
|  |             |                      | ART UNIT                    | PAPER NUMBER     |
|  |             |                      | 3738                        | 22               |

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/917,058             | MURRAY ET AL.       |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Brian E Pellegrino     | 3738                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 27 January 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 22-38 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 19-21 and 39-42 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/04 has been entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for the new limitation "essentially free of exogenous thrombin".

Applicant has failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations, i.e. "essentially free of exogenous

thrombin" (M.P.E.P. 714.02). Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem under 35 U.S.C. 112, first paragraph, is corrected.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlen (WO 85/00511) in view of Prior et al. (6096309). Medlen discloses an implantable prosthesis for repairing a ligament defect with collagen used as a repair material and a mechanical bond using sutures is used in the method, page 14, lines 26-33. However, Medlen does not disclose using a specific collagen, such as collagen I, or a protein, a neutralizing agent or a platelet in the composition. Prior et al. teach compositions (col. 12) that include collagen I, a platelet, a protein (thrombin) and a neutralizing agent. Prior also teaches that these compositions are used in reconstructive surgery, col. 13, lines 15-17,23-26,29,31,32. It would have been obvious to one of ordinary skill in the art to substitute a composition comprising collagen I with a neutralizing agent, platelets and a protein as taught by Prior et al. in the method of repairing a ligament tear by Medlen in order to provide a more biologically responsive implant capable of controlling blood loss.

Claims 19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (WO 93/21857) in view of Prior et al. '309. Li et al. disclose a prosthetic ligament made of collagen I, page 14, paragraph 3. Li also discloses using a neutralizing agent with the collagen, page 15, paragraph 4 – page 16, paragraph 2. Prior is explained supra. However, Li et al. do not disclose using a platelet or protein in the collagen material. It would have been obvious to one of ordinary skill in the art to add additional components such as platelets and proteins in the collagen material as taught by Prior et al. in the method of repairing a ligament tear by Li et al. in order to provide a more biologically responsive implant capable of controlling blood loss.

Claims 39,40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlen in view of Prior et al. '309 as applied to claim 19 above, and further in view of Bell et al. '292. Medlen as modified by Prior is explained supra. Bell teaches to include proteins, such as fibronectin or laminin in the extracellular matrix, col. 11, lines 38-45. It would have been obvious to one of ordinary skill in the art to substitute proteins in the composition and use one such as fibronectin as taught by Bell et al. in the method of Medlen and modified in view of Prior such that it provides a more adhesive like composition to aid in clotting because of the known properties of fibronectin.

Claims 41,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medlen in view of Prior et al. '309 as applied to claim 19 above, and further in view of Weadock (6129757). Medlen as modified by Prior is explained supra. Weadock teaches a composition that includes a gene therapy agent, such as a genetically altered cell and can be related to clot factors, col. 7, lines 21-55. It would have been obvious to

one of ordinary skill in the art to incorporate a genetically altered cell in the composition and use one that may relate to clotting as taught by Weadock in the method of Medlen and modified in view of Prior such that it provides the ability to control clotting.

***Response to Arguments***

Applicant's arguments with respect to claim 19 have been considered but are moot in view of the new ground(s) of rejection. Regarding the Li reference, please note that Li does disclose contacting ruptured tissue, since bone is considered hard tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8am to 5:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

TC 3700, AU 3738

Brian E. Pellegrino

*Brian E. Pellegrino*